Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D1052366	09/08/2022
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric Partners Of Stafford, Pc	110 Soaring Eagle Drive, Stafford, VA	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	An announced CLIA recertification survey was conducted at Pediatric Partners of Stafford, PC on September 8, 2022 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The specific deficiency is as follows:
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of policies and procedures, quality control (QC) records, and an interviews, the laboratory failed to follow their policy for QC statistics review in order to monitor, assess and correct problems with the hematology analyzer and complete blood count (CBC) QC materials for twenty-two (22) of 22 months (timeframe reviewed November 2020 until date of survey, September 8, 2022). Findings include: 1. Review of the laboratory's policies and procedures revealed a "Triannual Quality Assurance Checklist" to monitor, assess and correct problems with the Horiba Micros 60 hematology analyzer that stated "Quality Control-the required controls, calibrations and maintenance have been performed and reviewed." 2. Review of the "Triannual Quality Assurance Checklist" for January 2021, May 2021, September 2021, January 2022 and May 2022 revealed documentation of a "Y (yes)" response for "Quality Control-the required controls, calibrations and maintenance have been performed and reviewed." 3. Review of the laboratory's CBC QC records from November 2020 until the date of survey, September 8, 2022, revealed a lack of documentation of review of CBC QC records for 22 of 22 months reviewed. The inspector requested to review documentation of the CBC QC review from November

	2022 until the date of the survey, September 8, 2022. The laboratory provided no documentation to review. At approximately 11:30 AM on September 8, 2022, the nurse manager stated they did not realize they needed to print-out CBC QC records for the laboratory director's review. 4. In an exit interview with the nurse manager and testing personnel on September 8, 2022 at approximately 12:15 PM, the above findings were confirmed.